
Announcing Regional Workshops on **STABILITY TESTING AND CONTROL** Avoiding Stability Problems

<u>New Jersey</u>	<u>Puerto Rico</u>	<u>Missouri</u>	<u>California</u>
June 28, 1999 Completed. Successful Meeting!	July 19, 1999 Completed. Successful Meeting!	August 2, 1999 St. Louis Marriott Pavilion Hotel St. Louis, MO 314-421-1776	August 16, 1999 Manhattan Beach Marriott Hotel Manhattan Beach, CA 310-546-7511

Presented by:

Consumer Healthcare Products Association (CHPA)
Food and Drug Administration (FDA)
Pharmaceutical Research and Manufacturers of America (PhRMA)
Generic Pharmaceutical Industry Association (GPIA)
National Association of Pharmaceutical Manufacturers (NAPM)
National Pharmaceutical Alliance (NPA)
United States Pharmacopeia (USP)

Stability and stability-related issues have been the prominent cause of drug product recalls in the past two years. Through this joint FDA/industry educational program, the root causes of these recalls will be addressed, and experienced experts will provide solutions.

The educational workshops will address a broad range of issues related to stability. Both FDA and industry speakers will be featured at the workshops. FDA and the associations are encouraging broad attendance from pharmaceutical companies of all sizes. To help make it easy, the registration fee is being held to only \$250 per person, including lunch, and the workshops will be presented four times, in the East, the Midwest, the West, and Puerto Rico, all in the summer of 1999. Further details are on the following pages.

STABILITY TESTING AND CONTROL

FACULTY

Mark S. Alasandro
Associate Director
Analytical R & D
DuPont Life Sciences Enterprise

Kevin Bradley
Manager, Support to Marketed Products - Analytical
McNeil Consumer Healthcare

William W. Bradley
Vice President – Technical Affairs
Consumer Healthcare Products Association

Scott Buell, Ph.D. ✦ (St. Louis)
Manager, Quality Control Analytical Services
Glaxo Wellcome Inc.

Carol Easter (Panel)
Senior Manager, Stability Operations
Merck & Co., Inc.

John Ferrantello
Associate Director of Stability Services
Research & Technology
Block Drug Company, Inc

Kenneth J. Furnkranz * (Puerto Rico)
Chemist, Office of Generic Drugs
Food and Drug Administration

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Associate Director
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Food and Drug Administration

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Drug Investigator
San Juan District
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Vice President and Director
Division of Standards Development
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Ali H. Al Hakim, Ph.D. * (St. Louis)
Chemist, Office of New Drug Chemistry
Food and Drug Administration

Lori S. Henning ✦ (Puerto Rico)
Director, Compendial Documentation
Wyeth-Ayerst Global Pharmaceuticals

Robert V. Kasubick, Ph.D.
Vice President of Operations
Oakwood Laboratories, L.L.C.

Herbert Letterman, Ph.D. + (New Jersey, California)
Consultant
Member of the Advisory Committee to the USP PDS Subcommittee

Jai Mehta
President
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Abita Nanda (New Jersey)
Field Investigator
New Jersey District
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Shrikant N. Pagay, Ph.D. * (California)
Chemist, Office of New Drug Chemistry
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Associate Director
Regulatory and Analytical Sciences – Stability Department
Merck & Co., Inc.

Barry Rothman
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

Robert H. Seevers, Ph.D., * (New Jersey)
Chemist, Office of New Drug Chemistry
Chairperson of the CDER Stability Committee
Food and Drug Administration

* FDA Draft Guidance+ USP Issues ✦ “Controlling Factors”

The Food and Drug Administration, along with the USP and the five most representative drug trade associations is presenting an educational series on important aspects of stability. Whether you are new to the field of stability testing and evaluation, or have vast experience in the area, you and your company can benefit from this workshop. You will not only hear about the stability controversy, you will be able to interact with key FDA officials and industry experts, and give your own opinions.

The educational objectives of the workshops are to:

- ◆ Learn all about the FDA Draft Guidance for Industry on Stability
- ◆ Learn how to make sure your methods are stability indicating
- ◆ Learn different methods for establishing an expiry date
- ◆ Learn when, and when not, to use the Arrhenius equation
- ◆ Learn the stability issues surfacing in the United States Pharmacopeia
- ◆ Learn what FDA sees as stability problems
- ◆ Learn how to control factors that affect stability, and avoid recalls
- ◆ Learn how to label your products for storage to comply with various rules and regulations
- ◆ Learn how to avoid stability problems with your products

STABILITY TESTING AND CONTROL

Avoiding Stability Problems

Program

8:00 a.m.	Welcomes and Introductions	<i>William W. Bradley</i> <i>Vice President – Technical Affairs</i> <i>Consumer Healthcare Products Association</i> <i>FDA District Director</i>
8:10 a.m.	FDA Draft Stability Guidance for Industry	<i>Representative from</i> <i>Stability Coordinating Committee</i> <i>Center for Drug Evaluation & Research</i> <i>Food and Drug Administration</i>
9:00 a.m.	Practical Considerations Hybrid conditions	<i>John Ferrantello</i> <i>Associate Director of Stability Services</i> <i>Research & Technology</i> <i>Block Drug Company, Inc.</i>
	Packaging considerations	<i>Kevin Bradley</i> <i>Manager, Support to Marketed Products - Analytical</i> <i>McNeil Consumer Healthcare</i>
	Stability-indicating test methods	<i>Mark S. Alasandro</i> <i>Associate Director, Analytical R&D</i> <i>DuPont Life Sciences Enterprise</i>
	Use of the Arrhenius equation	<i>Robert Kasubick, Ph.D.</i> <i>Vice President of Operations</i> <i>Oakwood Laboratories, L.L.C.</i>
10:00 a.m.	BREAK	
10:30 a.m.	USP Stability and Storage Issues	<i>Lee T. Grady</i> <i>Vice President and Director</i> <i>Division of Standards Development</i> <i>United States Pharmacopeial Convention</i>
11:15 a.m.	Round Table Discussion and Q&A	<i>FDA, USP, Industry Representatives</i>
12:00 noon	LUNCH	
1:15 p.m.	Background on Stability Compliance Problems	<i>Barry Rothman</i> <i>Office of Compliance</i> <i>Center for Drug Evaluation and Research</i> <i>Food and Drug Administration</i> <i>FDA Field Investigator</i>
2:15 p.m.	Controlling Factors that Affect Stability	<i>Speakers for this subject will differ by location. They are identified by the symbol ♣ on the faculty list</i>
2:40 p.m.	BREAK	
3:00 p.m.	Label Storage Statements and Stability	<i>Jai Mehta</i> <i>President</i> <i>JM Pharma</i>
3:20 p.m.	Panel Discussion and Q&A	<i>All Speakers</i>
4:30 p.m.	Adjournment	

STABILITY TESTING AND CONTROL

Avoiding Stability Problems

Who Should Attend

- ◆ Regulatory managers
- ◆ Those with responsibility for:
 - NDA compilation
 - setting expiry dates
 - stability testing
 - stability evaluation
 - ensuring stability
 - labeling
 - problem solving
 - writing SOPs

**GET HOTEL
RESERVATIONS
IN EARLY!**

<u>New Jersey</u> June 28, 1999 Completed. Successful Meeting!	<u>Puerto Rico</u> July 19, 1999 Completed. Successful Meeting! Fax 787-888-0000	<u>Missouri</u> August 2, 1999 St. Louis Marriott Pavilion Hotel St. Louis, MO Ph. 314-421-1776 Fax 314-331-9269	<u>California</u> August 16, 1999 Manhattan Beach Marriott Hotel Manhattan Beach, CA Ph. 310-546-7511 Fax 310-796-0322
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Stability Testing and Control

Registration Form (Please print or type)

No phone registrations, please. No refunds will be made after 2 weeks prior to the workshop. Substitutions will be accepted.
Contact hotel directly for room reservations.

MAKE CHECKS PAYABLE TO CHPA
For your convenience, CHPA accepts
MasterCard, VISA, and American
Express credit cards. Mail or fax
completed registration form with your
payment to:

Mary McDonald
CHPA
1150 Connecticut Ave., N.W.
Washington, DC 20036

Phone 202-429-9260
Fax 202-223-6835

Registration fee: \$250.00

Name _____

Nickname (for badge) _____ Title _____

Company _____

Address _____

City _____ State _____ Zip _____

Phone _____ Fax _____

E-mail _____

☐ VISA

☐ MasterCard

☐ AmEx

☐ Check

Credit card # _____ Exp. Date _____

Signature _____

Name as it appears on card: _____

I am registering for (please ✓ one)

- ☐ **June 28, East Rutherford, NJ;** Sheraton Meadowlands 201/896-0500
☐ **July 19, Rio Grande, PR;** Westin Rio Mar Beach Resort 787/888-6612
☐ **August 2, St. Louis, MO;** Marriott Pavilion Hotel 314/421-1776
☐ **August 16, Manhattan Beach, CA** Manhattan Beach Marriott 310/546-7511